



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DLK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/077,194	12/04/98	BOHN	02481.1596

HM12/0616

FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
FRANKLIN SQUARE BLDG SUITE 700
1300 I STREET N W
WASHINGTON DC 20005-3315

EXAMINER
KIM, V

ART UNIT
1614

PAPER NUMBER
6

DATE MAILED: 06/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

JUN 17 1999

RECEIVED

JUN 17 1999

FINNEGAN, HENDERSON, FARABOW,
GARRETT AND DUNNER, LLP

Pocketed 6-17-99 Attorney CFE-MCF 525
Case 2481-1596
Due Date 9-16-99 ✓/EJA
Action 3 mo 11/20/99 ✓/EJA
By BAE ✓/EJA

Office Action Summary

Application No.
09/077,194

Applicant(s)
Bohn et al

Examiner
Vickie Kim

Group Art Unit
1614



☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 14-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 14-31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

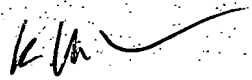
☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152


KEITH D. MacMILLAN
PRIMARY EXAMINER

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

DETAILED ACTION

Status of Application

1. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 119(a)-(d), has been filed in parent Application No. Germany 19639818.5, filed on September 27, 1996.

Claims 1-13 are canceled. And claims 14-31 are added by applicant's preliminary amendment. Claims 14-31 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 27 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Dittmar et al (US 4,185,106).

Claims read on a pharmaceutical composition comprising a component which contains 1-hydroxy-2-pyridone as a main moiety (note that this said components are generally called, 1-hydroxy-2-pyridones), and further comprising optionally at least one anionic, cationic, nonionic, or amphoteric surfactant, or a mixture thereof, and the preparation of the said composition.

Dittmar et al. (US'106) teach various pharmaceutical compositions and the preparation comprising 1-hydroxy-2-pyridones of the general formula which required by the instant claims:

Art Unit: 1614

See abstract. Dittmar et al. also teach a pharmaceutical compositions comprising 1-hydroxy-2-pyridones in combination. Dittmar et al. disclose the combination of the 1-hydroxy-2 pyridones composition and surfactants (e.g. anionic, cationic, non-ionic and amphoteric). See column 5, lines 1-68. Claim 29-30, the concentration of pyridones, are further taught in column 7, lines 33-44.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Dittmar et al. (US 4,185,106) in view of Lohaus et al. (US 4,797,409).

Dittmar et al. (US'106) teach various pharmaceutical compositions and the preparation comprising 1-hydroxy-2-pyridones of the general formula which required by the instant claims:

Art Unit: 1614

See abstract. Dittmar et al. also teach a pharmaceutical compositions comprising 1-hydroxy-2-pyridones in combination. Dittmar et al. disclose the combination of the 1-hydroxy-2 pyridones composition and surfactants (e.g. anionic, cationic, non-ionic and amphoteric). See column 5, lines 1-68. Claim 29-30, the concentration of pyridones, are further taught in column 7, lines 33-44.

Claims could be different from Dittmar's reference when R4 is substituted with a radical of formula II because there are certain species of R4 are not listed in the Dittmar et al's reference (e.g. R4= a radical of formula II).

Lohaus et al. teach a process for certain 1-hydroxy-2-pyridones preparation which is required by the instant claims.

It would have been obvious to one of ordinary skill in the art to substitute a radical of formula II for R4 position because the new substituted formulations would be distinguished by increased their fungicidal activity and a retention time at the site of infection. One would have been motivated to combine these references because both teachings are drawn to 1-hydroxy-2-pyridones which share general chemical and physical properties and even increase benefits by adding antibacterial and antiviral properties.

7. Claims 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohaus et al. (US 4,797,409) and Dittmar et al. (US 4,185,106) in view of Yoshimasa (The sebum lipid assimilation...: JSCCJ-1988).

Art Unit: 1614

Lohaus et al (US'409) and Dittmar et al. (US'106) teach various pharmaceutical compositions and the preparation comprising 1-hydroxy-2-pyridones of the general formula which required by the instant claims as mentioned above. The therapeutic effect from these formulas are also taught. Lohaus et al. teach excellent topical antimycotic(e.g. yeast, fungi etc.); antibacterial and antiviral properties of these said compositions. See column 6, lines 45-column 7, lines 3.

In addition, Dittmar et al (US '106) specify their activity as antidandruff agent.

Claims differ because seborrheic dermatitis which is required by the instant claims, are not taught by the cited references.

It would have been obvious to one of ordinary skill in the art to use these said 1-hydroxy-2-pyridones to treat seborrheic dermatitis when Lohaus and Dittmar's reference is taken in view of Yoshimasa and Saint-Leger et al.'s references.

Yoshimasa teach **P. ovale**(Yeast) is responsible for seborrheic dermatitis and dandruff condition. And it teach antidandruff agents(pyridone derivatives: piroctone olamine) is the most effective inhibitor of **P. ovale**.

One would have been motivated to use these said pyridones composition to treat seborrheic dermatitis because both teaching drawn to the conclusion, that is 1-hydroxy-2-pyridones are the most effective agents to treat seborrheic dermatitis and the combination with variable surfactants extends the opportunities to make different products to fit on individual's need(e.g. shampoo, lotion, cream etc.). One would have been motivated to do, with reasonable

Art Unit: 1614

expectation of success, because all these teachings are drawn to the same technical fields and pertinent to the problem with which applicant is concerned. MPEP 2141.01(a).

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lohaus and Dittmar et al's references applied to claims above, and further in view of Kamegai et al.(US 5,753,600).

Lohaus and Dittmar teachings are mentioned above. A pharmaceutical composition required by the instant claims, are taught in the cited references.

Claims differ because the required PH of compositions are not taught in the cited references. Dittmar mentioned one of advantages of their patented invention regarding PH level: See column 9, lines 20-42. That is their patented composition could be lower than PH=7.5. However, it still have not specify the PH range of their patented compositions.

Kamegai et al.(US 600) teach a pharmaceutical composition comprising 1-hydroxy-2-pyridones, could be adjusted to 2-10, preferably to 4-8 using an alkali or acid agent.

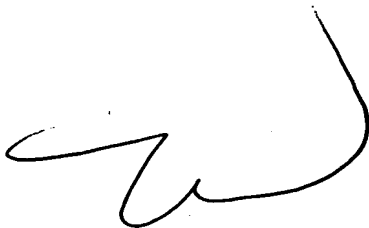
It would have been obvious to adjust a said composition in proper PH range because the certain products would have acidic additives and need to be formulated in acidic condition. One would have been motivated to modify Lohaus and Dittmar's teachings with Kamegai et al.'s teaching because all these teachings are pertinent and analogous in same technical fields.

Conclusion

9. All the pending claims 14-31 are rejected.


Art Unit: 1614

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Vickie Kim* whose telephone number is (703)305-1675.



Vickie Kim, patent examiner

June 9, 1999



KEITH D. MacMILLAN
PRIMARY EXAMINER